UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------------------|----------------------|---------------------|------------------|
| 10/637,213 | 08/07/2003 | Alex Alden Peterson | 293/037Cont 3 | 4084 |
| 1473 FIGH & NEAN | 7590 08/23/2007 JE IP GROUP | | EXAMINER | |
| FISH & NEAVE IP GROUP ROPES & GRAY LLP | | | YABUT, DIANE D | |
| 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704 | | | ART UNIT | PAPER NUMBER |
| TIEVI TOTAL, | 111 10000 0701 | | 3734 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 08/23/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| e e e e e e e e e e e e e e e e e e e | | |
|--|--|--|
| • | Application No. | Applicant(s) |
| | 10/637,213 | PETERSON ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Diane Yabut | 3734 |
| The MAILING DATE of this communication a Period for Reply | appears on the cover sheet w | ith the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNION 1.136(a). In no event, however, may a cod will apply and will expire SIX (6) MON tute, cause the application to become Al | CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). |
| Status | , | |
| 1) ☐ Responsive to communication(s) filed on 31 2a) ☐ This action is FINAL . 2b) ☐ TI 3) ☐ Since this application is in condition for allow | his action is non-final. vance except for formal mat | · |
| closed in accordance with the practice unde | er <i>Ex par</i> te <i>Quayle</i> , 1935 C.C | D. 11, 453 O.G. 213. |
| Disposition of Claims | · · | |
| 4) ○ Claim(s) 83-90 is/are pending in the applicate 4a) Of the above claim(s) is/are withd 5) □ Claim(s) is/are allowed. 6) ○ Claim(s) 83-90 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and | rawn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and a applicant may not request that any objection to the Replacement drawing sheet(s) including the correct of the sheet of the s | ccepted or b) objected to he drawing(s) be held in abeyarection is required if the drawing | nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreignation a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a least | ents have been received. ents have been received in A riority documents have been eau (PCT Rule 17.2(a)). | Application No received in this National Stage |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) | Danas Na/ | Summary (PTO-413) |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | · — | s)/Mail Date nformal Patent Application |

DETAILED ACTION

This action is in response to applicant's amendment received 05/31/07.

Response to Declaration Under 37 CFR 1.132

In the examiner's previous Office Action dated 03/07/2007 it was stated that clarity was necessitated regarding the Declaration dated 11/13/06 by Todd A. Berg pursuant to 37 C.F.R. § 1.132 stating that anything shown in the '036 patent [the prior art used by the examiner to reject the claims under 35 U.S.C. 102(e)] that is claimed in the 10/637213 or '213 application [the present application] was derived from the inventors named on the 09/016721 or '721 application [the parent of the '036 patent], as seen on lines 4-8, page 3 of the declaration. The examiner requested the applicant provide clarification as to which inventors contributed to the claims of the present application '213.

In the remarks dated 05/31/07, attorney Robert R. Jackson has confirmed with inventor Paul J. Hindrichs that the inventors named on the present application, on the original priority application (now U.S. patent 6,152,937), and on the intervening priority application (U.S. patent 6,673,084), have remained the same: namely Alex A. Peterson, Paul J. Hindrichs, Mark D. Wahlberg, Todd A. Berg, and Jon P. St. Germain.

However, since the inventorship changes from

the '721 application:

(Berg, Peterson, Wahlberg, St. Germain),

to the '036

the '036 patent:

(Berg, Peterson, Wahlberg),

to

the '213 application:

(Berg, Peterson, Wahlberg, St. Germain, Hindrichs),

Art Unit: 3734

the examiner is unclear as to whether or not inventors Hindrichs and/or St. Germain contributed to the present application claims, and it must be proven that the joint invention of the '213 application was made first, and thereafter described in the '036 patent, so that it is clear that the '036 patent is Applicant's own work. Otherwise, the rejection of Claims 83-90 as stated in the Office Action mailed 09/12/2006 in view of Berg (U.S. Patent No. 6,391,036) is proper and will be reinstated.

See MPEP § 2136.05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 83, 85, and 87-90 are rejected under 35 U.S.C. 102(b) as being 2. anticipated by Kaster (U.S. Patent No. 5,234,447).
- Kaster discloses a connector for use in making an artificial, fluid-tight, Claim 83: hollow, annular connection between an end portion of a tubular graft conduit and a side wall of a tubular body conduit in a patient via an artificially created aperture in the side wall of the tubular body conduit so that the tubular graft conduit extends from the tubular body conduit outside of the tubular body conduit and the patient's body fluid can flow between lumens of the tubular graft conduit and the tubular body conduit via the connection, the connector comprising a structure 12 which is annularly continuous and

Application/Control Number: 10/637,213

Art Unit: 3734

configured for disposition annularly around the outside of the tubular graft conduit, a plurality of first members 43 and a plurality of second members 44 extending from the structure in an annular array which is substantially concentric with the structure, the first and second members being resiliently biased to extend substantially radially out from the structure and being elastically deflectable substantially parallel to a central longitudinal axis of the structure, the first members being configured to pass through the side wall of the tubular graft conduit at respective locations that are spaced from one another around the side wall of the tubular graft conduit, and the first and second members being further configured to reach respective locations on the side wall of the tubular body conduit that are spaced annularly around the aperture when the connector is in use and the first and second members are extending substantially radially out from the structure (Figures 10, 14-19).

Claim 84: Kaster discloses the first 43 and second 44 members extending from respective first and second axially spaced portions of the structure, in that the edges of 46 are axially spaced (Figure 10).

Claim 85: Kaster discloses when the first 43 and second 44 members are being deflected substantially parallel to the central longitudinal axis of the structure, they extend in respective opposite directions away from the structure (Figures 14-19).

Claim 87: Kaster discloses the first 43 and second 44 members being further configured for disposition on respective opposite sides of the side wall of the tubular body conduit when the connector is in use and the first and second members are extending substantially radially out from the structure (Figures 14-19).

Application/Control Number: 10/637,213

Art Unit: 3734

<u>Claims 88-89</u>: Kaster discloses the structure being configured for annular and axial flexibility (Figures 10, 14-19).

<u>Claim 90</u>: Kaster discloses the structure and the first and second members being all one piece (Figure 8).

Claim Rejections - 35 USC § 103

3. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kaster** (U.S. Patent No. **5,234,447**).

Claim 86: Kaster discloses the claimed device except for the connector comprising nitinol. It would have been obvious to one of ordinary skill in the art at the time of invention to provide nitinol as a material for the connector since nitinol is well known for its compatibility with the body.

Response to Arguments

Applicant's arguments in regards to the Kaster reference filed 31 May 2007 have been fully considered but they are not persuasive.

Applicant argues that Kaster's device does not disclose an "annularly continous connector structure, and that it is only a C-shaped element shown in Figure 10. The examiner asserts that the element 46 of Kaster in Figure 10 does in fact show an annulary continuous connector to the extent that the elected Species 8 (Figures 21a-21b) in the present application appears to be annularly continuous (particularly in

Application/Control Number: 10/637,213

Art Unit: 3734

Figures 21b-c which also demonstrates a C-shaped element), and the continuation of the annular element seems to depend on how deformed the connector is deformed, in either Kaster or the present application.

The applicant also argues that the Kaster teaches a plastic staple that undergoes plastic deformation, unlike the present application's connector that demonstrates elastic deformation, and there would be no motivation for anyone to use an elastically deformable material such as nitinol in what Kaster teaches. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one of ordinary skill in the art to modify the connector of Kaster by using an elastically deformable material such as nitinol, since it is a common, adjustable biocompatible material used in medical devices.

Conclusion

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 3734

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/ Hayer